

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
P.O. Box 1450, Washington, DC 20590-1450 • (800) 787-4747 • (202) 707-8300

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.			
Substitute for form 1449/PTO		<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		Application Number	10/586,045
		§371 Date	June 12, 2007
		First Named Inventor	SOHN, Jung-Hoon
		Art Unit	1632
		Examiner Name	<i>To be assigned</i>
Sheet	1	of	1
		Attorney Docket Number	2472_0010000/EKS/BNC

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Sheet 1 of 1

*Complete if Known*

Application Number	10/586,045
§371 Date	June 12, 2007
First Named Inventor	SOHN, Jung-Hoon
Art Unit	1632
Examiner Name	To be assigned
Attorney Docket Number	2472_0011000/EV S

---

**U.S. PATENT DOCUMENTS**

---

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (If Known)	MM-DD-YYYY		
/ADS/	US1	5,037,760	08/06/1991	Smith <i>et al.</i>	
/ADS/	US2	5,536,637	07/16/1996	Jacobs	
/ADS/	US3	5,952,171	09/14/1999	McCarthy <i>et al.</i>	
/ADS/	USA4	6,150,098	11/21/2000	Zhang <i>et al.</i>	
/ADS/	US5	6,228,590 B1	05/08/2001	Baker	
/ADS/	US6	2002/0127557 A1	09/12/2002	Tan <i>et al.</i>	
/ADS/	US7	6,548,633 B1	04/15/2003	Edwards <i>et al.</i>	
/ADS/	US8	2004/0110939 A1	06/10/2004	Edwards <i>et al.</i>	
/ADS/	US9	7,029,842	04/18/2006	Duffner <i>et al.</i>	

---

**FOREIGN PATENT DOCUMENTS**

---

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T#
		Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>4</sup> (if known)				
	FP1	WO 97/40146 A1	10/30/1997	Genetics Institute, Inc.		
/ADS/	FP2	WO 99/49028 A1	09/30/1999	Genentech, Inc.		
	FP3	WO 01/00806 A2	01/04/2001	Genset		
/ADS/	FP4	WO 01/77315 A1	10/18/2001	Novozymes A/S		
/ADS/	FP5	EP 1 170 366 A1	01/09/2002	Genetics Institute, Inc.		
/ADS/	FP6	WO 02/072821 A2	09/19/2002	Incyte Genomics, Inc.		
	FP7	WO 2007/015178 A2	02/08/2007	Korea Research Institute of Bioscience and Biotechnology		

787272 1

Examiner Signature	/Amber D. Steele/	Date Considered	11/06/2009
--------------------	-------------------	-----------------	------------

**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 601. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional). \* See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>1</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \* Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case circumstances. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. Instead, send them directly to the USPTO's Communications Division, P.O. Box 1450, Alexandria, VA 22313-1450.

**If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
				Application Number	10/586,045
				§371 Date	June 12, 2007
				First Named Inventor	SOHN, Jung-Hoon
				Art Unit	1632
				Examiner Name	To be assigned
				Attorney Docket Number	2472.0010000/EKS/BNC
Sheet	1	of	4		

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T <sup>2</sup>
/ADS/	NPL1	Baldari, C., et al., "Differential stability of human interleukin 1 beta fragments expressed in yeast," <i>Protein Eng.</i> 1:433-437, JRL Press Limited (1987)			
/ADS/	NPL2	Broekhuijsen, M.P., et al., "Secretion of heterologous proteins by <i>Aspergillus niger</i> : Production of active human interleukin-6 in a protease-deficient mutant by KEX2-like processing of a glucoamylase-hIL6 fusion protein," <i>J Biotechnol.</i> 31:135-145, Elsevier Science Publishers B.V. (November 1993)			
/ADS/	NPL3	Contreras, R., et al., "Efficient KEX2-like Processing of a Glucoamylase-Interleukin-6 Fusion Protein by <i>Aspergillus Nidulans</i> and Secretion of Mature Interleukin-6," <i>Bio/Technology (N.Y.)</i> 9:378-381, Nature Pub. Co. (April 1991)			
/ADS/	NPL4	Crosier, P.S., et al., "In Situ Hybridization Screen in Zebrafish for the Selection of Genes Encoding Secreted Proteins," <i>Developmental Dynamics</i> 222:637-644, Wiley-Liss, Inc. (2001)			
/ADS/	NPL5	Dorner, A.J., et al., "Overexpression of GRP78 mitigates stress induction of glucose regulated proteins and blocks secretion of selective proteins in Chinese hamster ovary cells," <i>The EMBO Journal</i> 11:1563-1571, Oxford University Press (1992)			
/ADS/	NPL6	Dorner, A.J., et al., "Reduction of Endogenous GRP78 Levels Improves Secretion of a Heterologous Protein in CHO Cells," <i>Molecular and Cellular Biology</i> 8:4063-4070, American Society for Microbiology (1988)			
/ADS/	NPL7	Downing, K.J., et al., <i>Staphylococcus aureus</i> nuclease is a useful secretion reporter for mycobacteria," <i>Gene</i> 239:293-299, Elscience Science B.V. (1999)			
/ADS/	NPL8	Eckart, M.R. and Bussineau, C.M., "Quality and authenticity of heterologous proteins synthesized in yeast," <i>Curr Opin Biotechnol.</i> 7:525-530, Current Biology Ltd. (October 1996)			
/ADS/	NPL9	Ferguson, D.A., et al., "Selective Identification of Secreted and Transmembrane Breast Cancer Markers using <i>Escherichia coli</i> Ampicillin Secretion Trap," <i>Cancer Res</i> 65:8209-8217, American Association for Cancer Research (2005)			
/ADS/	NPL10	Galliciotti, G., et al., "Signal-sequence Trap in Mammalian and Yeast Cells: A Comparison," <i>J. Membrane Biol.</i> 183:175-182, Springer-Verlag (2001)			

Examiner Signature	/Amber D. Steele/	Date Considered	11/06/2009
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
				Application Number	10/586,045
				§371 Date	June 12, 2007
				First Named Inventor	SOHN, Jung-Hoon
				Art Unit	1632
				Examiner Name	<i>To be assigned</i>
Sheet	2	of	4	Attorney Docket Number	2472.0010000/EKS/BNC

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published			T <sup>2</sup>
/ADS/	NPL11	Goo, J.H., et al., "Selection of <i>Arabidopsis</i> genes encoding secreted and plasma membrane proteins," <i>Plant Molecular Biology</i> 41:415-423, Kluwer Academic Publishers (1999)			
/ADS/	NPL12	Gouka, R.J., et al., "Efficient production of secreted proteins by <i>Aspergillus</i> : progress, limitations and prospects," <i>Appl Microbiol Biotechnol.</i> 47:1-11, Springer-Verlag (January 1997)			
/ADS/	NPL13	Harmsen, M.M., et al., "Overexpression of binding protein and disruption of the <i>PMR1</i> gene synergistically stimulate secretion of bovine prochymosin but not plant Thaumatin in yeast," <i>Appl Microbiol Biotechnol.</i> 46:365-370, (November 1996)			
/ADS/	NPL14	Hayano, T., et al., "Protein disulfide isomerase mutant lacking its isomerase activity accelerates protein folding in the cell," <i>FEBS Lett.</i> 377:505-511, Federation of European Biochemical Societies (December 1995)			
/ADS/	NPL15	Hsu, T.-A., et al., "Effects of Co-expressing Chaperone BiP on Functional Antibody Production in the Baculovirus System," <i>Protein Expr Purif.</i> 5:595-603, Academic press, Inc. (December 1994)			
/ADS/	NPL16	Jacobs, K.A., et al., "A genetic selection for isolating cDNAs encoding secreted proteins," <i>Gene</i> 198:289-296, Elsevier Science B.V. (1997)			
/ADS/	NPL17	Jeenes, D.J., et al., "A truncated glucoamylase gene fusion for heterologous protein secretion from <i>Aspergillus niger</i> ," <i>FEMS Microbiol Lett.</i> 107:267-272, Federation of European Microbiological Societies (March 1993)			
/ADS/	NPL18	Kjeldsen, T., et al., "Prepro-Leaders Lacking N-linked Glycosylation for Secretory Expression in the Yeast <i>Saccharomyces cerevisiae</i> ," <i>Protein Expr Purif.</i> 14:309-316, Academic Press (December 1998)			
/ADS/	NPL19	Kjeldsen, T., et al., "Synthetic Leaders with Potential BiP Binding Mediate High-Yield Secretion of Correctly Folded Insulin Precursors from <i>Saccharomyces cerevisiae</i> ," <i>Protein Expr Purif.</i> 9:331-336, Academic Press (April 1997)			
/ADS/	NPL20	Klein, R.D., et al., "Selection for genes encoding secreted proteins and receptors," <i>Proc. Natl. Acad. Sci. USA</i> 93:7108-7113, National Academy of Sciences (July 1996)			

Examiner Signature	/Amber D. Steele/	Date Considered	11/06/2009
--------------------	-------------------	-----------------	------------

\*EXAMINER: Indicate reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with each communication to the examiner.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.96. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO			<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>			Application Number	10/586,045
			§371 Date	June 12, 2007
			First Named Inventor	SOHN, Jung-Hoon
			Art Unit	1632
			Examiner Name	To be assigned
Sheet	3	of	4	Attorney Docket Number
2472.0010000/EKS/BNC				

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published		T <sup>2</sup>
/ADS/	NPL21	Lee, J., et al., "Novel Secretion System of a Recombinant <i>Saccharomyces cerevisiae</i> Using an N-Terminus Residue of Human IL-1 $\beta$ as Secretion Enhancer," <i>Biotechnol. Prog.</i> 15:884-890, American Chemical Society and American Institute of Chemical Engineers (1999)		
/ADS/	NPL22	Lim, E.M., et al., "Identification of <i>Mycobacterium tuberculosis</i> DNA Sequences Encoding Exported Proteins by Using <i>phoA</i> Gene Fusions," <i>J. Bacteriol.</i> 177:59-65, American Society for Microbiology (January 1995)		
/ADS/	NPL23	MacConaill, L.E., et al., Investigation of Protein Export in <i>Bifidobacterium breve</i> UCC2003," <i>Appl. Environ. Microbiol.</i> 69:6994-7001, American Society for Microbiology (December 2003)		
/ADS/	NPL24	Makrides, S.C., "Strategies for Achieving High-Level Expression of Genes in <i>Escherichia coli</i> ," <i>Microbiological Reviews</i> 60:512-538, American Society for Microbiology (1996)		
/ADS/	NPL25	Monteoliva, L., et al., "Large-Scale Identification of Putative Exported Proteins in <i>Candida albicans</i> by Genetic Selection," <i>Eukaryotic Cell</i> 1:514-525, American Society for Microbiology (August 2002)		
/ADS/	NPL26	Muesch, A., et al., "A novel pathway for secretory proteins?" <i>TIBS</i> 15:86-88, Elsevier Science Publishers Ltd. (UK)(March 1990)		
/ADS/	NPL27	Roberts, I.N., et al., "Heterologous gene expression in <i>Aspergillus niger</i> : a glucoamylase-porcine pancreatic phospholipase A <sub>2</sub> fusion protein is secreted and processed to yield mature enzyme," <i>Gene</i> 122:155-161, Elsevier Science Publishers B.V. (December 1992)		
/ADS/	NPL28	Robinson, A.S., et al., "Protein Disulfide Isomerase Overexpression Increases Secretion of Foreign Proteins in <i>Saccharomyces cerevisiae</i> ," <i>Bio/Technology (NY)</i> 12:381-384, Nature Pub. Co. (April 1994)		
/ADS/	NPL29	Robinson, A.S., et al., "Reduction of BiP Levels Decreases Heterologous Protein Secretion in <i>Saccharomyces cerevisiae</i> ," <i>J. Biol. Chem.</i> 271:10017-10022, American Society for Biochemistry and Molecular Biology (1996)		
/ADS/	NPL30	Sagt, C.M.J., et al., "Introduction of an N-Glycosylation Site Increases Secretion of Heterologous Proteins in Yeasts," <i>Applied and Environmental Microbiology</i> 66:4940-4944, American Society for Microbiology (2000)		

Examiner Signature	/Amber D. Steele/	Date Considered	11/06/2009
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	10/586,045
				§371 Date	June 12, 2007
				First Named Inventor	SOHN, Jung-Hoon
				Art Unit	1632
				Examiner Name	To be assigned
Sheet	4	of	4	Attorney Docket Number	2472.0010000/EKS/BNC

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
/ADS/	NPL31	Schultz, L.D., et al., "Using Molecular Genetics to Improve the Production of Recombinant Proteins by the Yeast <i>Saccharomyces cerevisiae</i> ," <i>Ann NY Acad Sci.</i> 721:148-157, New York Academy of Sciences (May 1994)	
/ADS/	NPL32	Surpili, M.J., et al., "A yeast-based model system for cloning secreted and membrane proteins," <i>An Acad Bras Cienc</i> 74:599-608, Academia Brasileira De Ciencias (2002)	
/ADS/	NPL33	Takahashi, S., et al., "Function of the prosequence for in vivo folding and secretion of active <i>Rhizopus oryzae</i> lipase in <i>Saccharomyces cerevisiae</i> ," <i>Appl Microbiol Biotechnol.</i> 55:454-462, Springer Verlag (May 2001)	
/ADS/	NPL34	Tan, N.S., et al., "Engineering a novel secretion signal for cross-host recombinant protein expression," <i>Protein Eng.</i> 15:337-345, Oxford University Press (2002)	
/ADS/	NPL35	Wang, H. and Ward, M., "Molecular characterization of a PDI-related gene <i>prpA</i> in <i>Aspergillus niger</i> var. <i>awamori</i> ," <i>Curr Genet</i> 37:57-64, Springer-Verlag (January 2000)	
/ADS/	NPL36	Ward, P.P., et al., "A system for production of commercial quantities of human lactoferrin: a broad spectrum natural antibiotic," <i>Bio/Technology (NY)</i> . 13:498-503, (May 1995)	
/ADS/	NPL37	Ward, M., et al., "Improved Production of Chymosin in <i>Aspergillus</i> by Expression as a Glucoamylase-Chymosin Fusion," <i>Bio/Technology</i> 8:435-440, Nature Pub. Co. (1990)	
/ADS/	NPL38	Preliminary Amendment (unpublished) of Co-pending U.S. Non-Provisional Application No. 11/914,437 (U.S. Nat'l Phase of PCT/IB2006/003102, listed as FPT7), Int'l Filing Date: July 13, 2006, Sohn et al., (Our Ref.:2472.0020001)	
/ADS/	NPL39	International Search Report for International Appl. No. PCT/KR2004/003517, Korean Intellectual Property Office, mailed April 7, 2005	see note in Office action
/ADS/	NPL40	International Search Report for International Appl. No. PCT/IB2006/003102 (listed as FPT7), Korean Intellectual Property Office, mailed March 30, 2003	see note in Office action

787275\_1

Examiner Signature	/Amber D. Steele/	Date Considered	11/06/2009
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.